UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,656	08/05/2003	Richard L. Dunn	1195.323US1	6348

21186 7590 02/16/2011

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
02/16/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
request@slwip.com

Office Action Summary	Application No.	Applicant(s)	
	10/634,656	DUNN ET AL.	
	Examiner	Art Unit	
	ANDREW M. GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-18 and 20-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-18 and 20-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/2/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 12/2/2010.

2. In the reply, the applicant amended claims 1, 18, 21; cancelled claim 19; and added new claim 26.

3. Thus, claims 1, 3-18, 20-26 are pending for examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 5-8, 10-11, 13, 17, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al (5697918). Fischer discloses a coupling syringe system comprising: a first syringe (52) including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including a first syringe tip with an integral male end portion (54; Fig 5) and a locking ring (55), wherein the locking ring is spaced from an outer surface of the male end portion (55; Fig 5); a first syringe plunger (58) slidably disposed within the first syringe barrel, the first syringe plunger in fluid-tight engagement with an inner surface of the first syringe barrel; a second syringe (12) including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further including a second syringe tip (18; Fig 5) with an integral female end portion (18) and one or more

exteriorly protruding members (22) adapted to detachably fit the locking ring, wherein the female end portion has an opening defined by an opening wall, which supports the one or more exteriorly protruding members; and a second syringe plunger (14) slidably disposed within the second syringe barrel, the second syringe plunger in fluid-tight engagement with an inner surface of the second syringe barrel, wherein, when the first and second syringes are coupled, the male end portion is received by the opening of the female end portion, and the opening wall and the one or more exteriorly protruding members are received by the spacing between the locking ring and the outer surface of the male end portion, thereby allowing for a single, fluid tight attachment site configured for back and forth transfer of one or more compositions between the first syringe and second syringes (Figs 5-7; the arrangement is fully capable of back/forth transfer). For claim 3 (see Figs 5-7); claim 5 (threads 22, 55); claim 6 (fig 5-7); claims 7-8 (outward flanges (42; 57); claim 10-11 (threads 22, 55; Figs 5-7); claim 13 (wherein either the storage syringe or administration syringe has the dose medicament - Figs 5-7- fully capable of being a drug delivery system); claim 17 (Fig 5); claim 18 (Fig 5; wherein the bulk storage syringe is fully capable of being a single dose syringe - i.e. when the bulk storage has one dose left remaining to transfer to the administration syringe, then the bulk storage syringe is a single dose administration syringe); claim 20 (Fig 5). See response to arguments below.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 3-14, 17-18, 20-22, 25, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beller (5425580) in view of Fitoussi et al (5984373).

7. Beller discloses a coupling syringe system comprising: a first syringe (10) including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including a first syringe tip with an integral male end portion (Fig 4; col 4, lns 29-37); a first syringe plunger (Fig 4) slidably disposed within the first syringe barrel, the first syringe plunger in fluid-tight engagement with an inner surface of the first syringe barrel; a second syringe (6) including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further including a second syringe tip 1) with an integral female end portion (col 4, lns 1-21), wherein the female end portion has an opening defined by an opening wall, which supports the one or more exteriorly protruding members; and a second syringe plunger (Fig 4) slidably disposed within the second syringe barrel, the second syringe plunger in fluid-tight engagement with an inner surface of the second syringe barrel, wherein, when the first and second syringes are coupled, the male end portion is received by the opening of the female end portion, and the opening wall and the one or more exteriorly protruding members are received by the spacing between the locking ring and the outer surface of the male end portion, thereby allowing for a single, fluid tight attachment site configured for back and forth transfer of one or more compositions between the first syringe and second syringes (Fig 4; Summary). Further

disclosing the syringes being the same size (Fig 4) and one syringe having contrast medium (Summary) and the other syringe having air – acting as a drug administration system (Summary); a needle cannula and hub (col 3, lns 1-3). Also, with respect to claim 26, the examiner notes that the "mixing region" is only formed when the male and female portions are attached, so as long as the male and female portions are attachable and detachable, as taught by Beller, then the recitation of the mixing region configured to be at least partially detachable from the first and second dose syringe is met.

8. However, Beller discloses the invention substantially as claimed except for expressly disclosing a locking ring rotatable around the male luer for attaching to threads on a female luer. Fitoussie et al teaches that it is known to have a locking ring rotatable around the male luer for attaching to threads on a female luer (Figs 1-3b) for the purpose of providing a fluid tight connection between two different medical devices. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the male/female connection as taught by Beller with the locking ring and threads as taught by Fitoussie et al for the purpose of providing a fluid tight connection between two different medical devices. See response to arguments below.

9. Claims 15-16, 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beller in view of Fitoussie et al in further view of Cha et al (570717). Beller and Fitoussie disclose the invention substantially as claimed except for expressly disclosing compositions comprising leuprolide acetate, poly(DL-lactide-co-glycolide) and N-methyl-z-pyrrolidone to be mixed for subsequent administration to a patient. . Cha suggests

the mixing of leuprolide acetate, poly(DL-lactide-co- glycolide) and N-methyl-z-pyrrolidone to make a composition for injection into a patient column 1, line 65 - column 2, line 17 and column 2, line 45 - column 3, line 35). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Cha in the device of Beller and Fitoussie in order to achieve a mixing system that quickly and thoroughly mixes a desired composition where the mixed composition is contained in a syringe for patient injection for injecting a therapeutic agent in a biodegradable matrix with solvent present for ease of administration. Cha suggests the desirability of mixing these components for patient treatment. See response to arguments below.

Response to Arguments

2. Applicant's arguments with respect to the claims have been considered but are not persuasive.

3. The applicant argues that:

   i. Fischer fails to disclose a configuration for back and forth transfer of one or more compositions between first/second syringes as one of the syringes only contains an empty dose, not a composition.

4. In response to applicant's argument (i), the Examiner respectfully disagrees. The Examiner notes that the applicant has claimed "back and forth transfer of one or more compositions between the first and second syringes" in claim 1. Fischer discloses a composition stored in the bulk storage syringe. The Examiner notes that the bulk storage syringe is fully capable of being sized to contain a single dose along with the dose administration syringe (i.e. this is not the same as reciting the first and second

syringes are the same size), as the chamber of each syringe is variable via the plunger position and fully capable of being sized to contain a single dose. The back and forth transfer of one or more compositions is met by one composition being contained in the storage syringe and transferred to the dose administration syringe and the system is fully capable of transferring the composition back and forth between the two. There is no requirement in the claim that the second syringe contain any composition, only that one or more compositions may be transferred back and forth between the 1st/2nd syringes which Fischer teaches. The rejection is maintained.

ii. The proposed combination of Beller and Fitoussi would destroy the operability of such references for their respective intended purpose. Beller would not be able to be made by injection molding without eliminating the internal mixing chamber if it had the locking ring as taught by Fitoussi.

5. In response to applicant's argument (ii), the Examiner respectfully disagrees. One of ordinary skill in the art would recognize that injection molding techniques as known in the art are fully capable of manufacturing the Beller device with a locking ring as taught by Fitoussi. The mixing chamber of Beller is injection molded and then connected unreleasably to the connecting piece of a conventional syringe or produced as one piece with the syringe barrel. One of ordinary skill in the art would recognize that similarly the locking ring could be injection molded separately and attached to the conventional syringe and mixing chamber by adhesive or ultrasonic means. As Beller discloses molding the mixing chamber both with or separate from the syringe barrel, there is no teaching that requires the locking ring to be manufactured by injection

molding as a unitary piece with the syringe barrel and mixing chamber. Thus, the applicant's argument that to add a locking ring to the syringe of Beller would require the elimination of the mixing chamber is not persuasive. The Examiner also notes that the applicant has disclosed that is it well known to do this process (see ¶30 where the first syringe can be manufactured by independently molding the syringe and locking ring and then mounting the locking ring on the first syringe). The rejection is maintained.

iii. Beller and Fitoussi fail to disclose first and second syringe plungers being configured to move to a position at the distal end of the respective syringe as the mixing chamber of Beller is non-detachable from the first syringe and does not allow the first syringe plunger to move to the distal end of that syringe.

6. In response to the applicant's argument (iii), the Examiner notes that the applicant has not structurally defined the "distal end of the syringe." Here, Beller teaches a convention syringe and a plunger that is configured to move to a position at the syringe distal end. Attached to a first syringe is a mixing chamber, but there is no claim recitation that requires the mixing chamber to be considered part of the syringe to form its syringe distal end. Further, "at the first syringe distal end" is broad enough to include at the distal end of the first syringe's medicament chamber." There is no structural requirement that requires the distal end of the male/female end portions to form the distal end of the syringe. This makes sense because the applicant's plunger is only configured to move to the distal end of the syringe medicament chamber (e.g. Fig

6) and not to the distalmost end of the syringe tip and male/female portions. The rejection is maintained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767